

CLAIMS:

1. Use of an activator of NKT cells in the preparation of a medicament for inducing an immune response to soluble polypeptide antigen in an individual, wherein the medicament is for administration in conjunction with a TLR activator, with the proviso that, when the activator of NKT cells is a glycosylceramide, the TLR activator is not CpG or MPL.
- 10 2. Use of a TLR activator in the preparation of a medicament for inducing an immune response to soluble polypeptide antigen in an individual, wherein the medicament is for administration in conjunction with an activator of NKT cells, with the proviso that, when the activator of NKT cells is a glycosylceramide, the TLR activator is not CpG or MPL.
- 15 3. Use according to claim 1 or claim 2 wherein the activator of NKT cells is  $\alpha$ -GalCer.
- 20 4. Use according to claim 1 or claim 2 wherein the activator of NKT cells is OCH.
- 25 5. Use according to any one of claims 1 to 4, wherein the TLR is TLR3, TLR4, TLR5, TLR7 or TLR9.
6. Use according to claim 5, wherein the activator of TLR4 is MPL.
- 30 7. Use according to any one of claims 1 to 6, wherein the activator of NKT cells is administered up to about 2 hours before the polypeptide antigen is administered to said individual.
- 35 8. Use according to any one of claims 1 to 6, wherein the activator of NKT cells is administered up to about 8 hours

after the polypeptide antigen is administered to said individual.

9. Use according to any one of claims 1 to 6, wherein the activator of NKT cells and the polypeptide antigen are administered concurrently to said individual.

10. Use according to any one of claims 1 to 9, wherein the soluble antigen is a tumour antigen.

11. Use according to any one of claims 1 to 9 wherein the soluble antigen is a viral antigen.

12. Use according to any one of claims 1 to 9, wherein the soluble antigen is a bacterial antigen.

13. Use of OCH in the preparation of a medicament for inducing an immune response to soluble polypeptide antigen in an individual.

20 14. Use according to claim 13, wherein the OCH is administered up to about 2 hours before the polypeptide antigen is administered to said individual.

25 15. Use according to claim 13, wherein the OCH is administered up to about 8 hours after the polypeptide antigen is administered to said individual.

30 16. Use according to claims 13, wherein the OCH and the polypeptide antigen are administered concurrently to said individual.

17. Use according to any one of claims 13 to 16, wherein the soluble antigen is a tumour antigen.

18. Use according to any one of claims 13 to 16 wherein the soluble antigen is a viral antigen.

5 19. Use according to any one of claims 13 to 16, wherein the soluble antigen is a bacterial antigen.

10 20. Use of  $\alpha$ -GalCer in the preparation of a medicament for inducing an immune response to soluble polypeptide antigen in an individual, wherein the medicament is for administration in conjunction with CpG or MPL.

15 21. Use of  $\alpha$ -glucosylceramide in the preparation of a medicament for inducing an immune response to soluble polypeptide antigen in an individual, wherein the medicament is for administration in conjunction with CpG or MPL.

20 22. A composition comprising an activator of NKT cells and a TLR activator, with the proviso that, when the activator of NKT cells is a glycosylceramide, the TLR activator is not CpG or MPL.

23. A composition according to claim 22 wherein the activator of NKT cells is  $\alpha$ -GalCer.

25 24. A composition according to claim 22 wherein the activator of NKT cells is OCH.

25 25. A composition according to any one of claims 22 to 24, wherein the TLR is TLR3, TLR4, TLR5, TLR7 or TLR9.

30 26. A composition according to claim 25, wherein the activator of TLR4 is MPL.

27. A composition comprising  $\alpha$ -GalCer and MPL or CpG.

28. A composition comprising  $\alpha$ -glucosylceramide and MPL or CpG.

29. A composition according to any one of claims 22 to 28  
5 further comprising a purified soluble polypeptide antigen.

30. A composition comprising OCH and a purified soluble polypeptide antigen.

10 31. A composition according to claim 29 or claim 30, which composition is free of cells.

32. A composition according to any one of claims 29 to 31, wherein the soluble antigen is a tumour antigen.

15 33. A composition according to any one of claims 29 to 31, wherein the soluble antigen is a viral antigen.

20 34. A composition according to any one of claims 29 to 31, wherein the soluble antigen is a bacterial antigen.

35. A pharmaceutical composition comprising the composition of any of claims 22 to 34 and a pharmaceutically acceptable carrier or diluent.

25 36. The pharmaceutical composition of claim 35 wherein the carrier is a liposome.

30 37. Use of the composition of any of claims 22 to 34 or the pharmaceutical composition of claim 35 or claim 36 in a method of inducing an immune response in an individual.

35 38. A kit having first and second containers, wherein the first container comprises a composition comprising an activator of NKT cells, and the second container

comprises a composition comprising a TLR activator, with the proviso that, when the activator of NKT cells is a glycosylceramide, the TLR activator is not CpG or MPL.

5       39. A kit having first and second containers, wherein the first container comprises a composition comprising  $\alpha$ -GalCer, and the second container comprises a composition comprising CpG or MPL.

10      40. A kit having first and second containers, wherein the first container comprises a composition comprising  $\alpha$ -glucosylceramide, and the second container comprises a composition comprising CpG or MPL.

15      41. A kit according to any one of claims 38 to 40 which additionally has a third container, which container comprises a composition comprising a purified polypeptide antigen.

20      42. A kit having first and second containers, wherein the first container comprises a composition comprising OCH, and the second container comprises a composition comprising a purified polypeptide antigen.

25      43. A kit according to any one of claims 38 to 42 wherein any or all of said compositions further comprises a pharmaceutically acceptable carrier or diluent.